

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Hargens, et al.

APPLICATION NO.: 10/566,188

FILED: June 15, 2007

FOR: TASTE-MASKED COMPOSITION OF CATIONIC EXCHANGE RESIN

EXAMINER: Valdez, Deve E.

GROUP ART UNIT: 1796

CONFIRMATION NO.: 2101

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This Appeal Brief is filed in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed February 17, 2010 in response to Applicants Pre-Appeal Brief Request for Review submitted January 25, 2010 in response to the Final Office Action mailed January 5, 2010 which finally rejected then-pending claims 1-8.

This Appeal Brief is being timely filed therefore no fee is due.

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Real Party In Interest

The real party in interest is Novartis Consumer Health S.A. as evidenced by an Assignment recorded on Reel/Frame 024010/0034 on March 2, 2010.

Related Appeals and Interferences

There are no related appeals or interferences to the instant application.

Status of Claims

Claims 1-8 are pending, are finally rejected, and their rejection is appealed.
Claims 9-15 are canceled.

Status of Amendments

The Final rejection was mailed on January 5, 2010 and no amendments have been made subsequent to the final rejection.

Summary of Claimed Subject Matter

Independent claim 1 is directed to a process for producing a taste-masked composition. The taste-masked composition comprises an ionic active compound and a functionalized polymer matrix. The claimed process involves “loading said functionalized polymer matrix with [an] active compound to produce a loaded matrix, and washing said loaded matrix with a nonpolar solvent.”

Grounds of Rejection to be Reviewed on Appeal

Whether claims 1 and 2 are unpatentable under 35 U.S.C. §102(b) as being anticipated by EP 1175915.

Whether claims 3-8 are unpatentable under 35 U.S.C. §103(a) as being obvious over EP 1175915 in view of WO 01/70194, which corresponds to English language document U.S. Patent No. 7,067,116.

Argument

A. Introduction

As noted in the Summary of Claimed Subject Matter, Applicants' pending independent claim 1 is directed to a process for producing a taste-masked composition. The taste-masked composition includes an ionic active compound and a functionalized polymer matrix. The ionic active compound, which may have a poor taste, is loaded into the functionalized polymer matrix. The polymer matrix serves to prevent the ionic active compound from being tasted immediately in the mouth by chemically binding the active. The claimed process comprises a step of loading the matrix with the active to produce a loaded matrix and subsequently washing the loaded matrix with a nonpolar solvent. The loading step is typically performed by exposing the matrix to a solution of the active. The washing step "remove[s] unbound active compounds without causing competing dissociation of the bound active from the matrix." (See Specification at page 1, lines 23-25). If this washing step were not performed, then unbound active on the surface of the loaded matrix would be free to cause a poor taste.

B. The Rejection of Claims 1-2 as unpatentable under 35 U.S.C. §102(b) as being anticipated by EP 1175915.

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b) as anticipated by EP 1175915 (hereinafter '915).

Claim 1 recites a process including a loading and then a washing step. As explained in applicant's specification, the washing step is to remove unbound active from the loaded matrix. (See specification at page 1, lines 22-26).

The loading step involves exposing the matrix to a solution of the active to infuse the active into the matrix causing some of it to bind, and the subsequent washing step removes the unbound active which otherwise could impart poor taste to the loaded active. (See Specification at page 1, line 16 – page 2, line 8). To accomplish its purpose of "washing said loaded matrix" as recited in Claim 1, the claimed nonpolar solvent must not be another solution of the active, which would just re-coat the loaded matrix with

active. (See e.g., the Specification at page 4, last paragraph to page 5, first paragraph, Examples 1-5).

Reference '915 does not teach or suggest a washing step – it only teaches using an active-containing solution to load active into the matrix.

The examiner points to example 1 of the '915 reference as evidence of a washing step. In Example 1, a solution of an active (indomethacin) and a polar solvent (water) is added together in a glass vial and shaken. The examiner takes the position that the “shaking step of ['915] is equivalent to the ‘washing step’ of the invention.” (See Office Action of June 15, 2007, at page 6). It isn't. Applicant's claims and specification are very clear that a washing step is the step subsequent to loading to remove unbound active. The '915 reference only discloses a loading step because the only solution described in '915 in Example 1 is a solution including the active. In fact, Example 1 of '915 is titled “water-only loading” (emphasis added).

Because the washing step recited in claim 1, and by dependent claim 2 is not found in the '915 reference, this rejection should be reversed.

C. The rejection of claims 3-8 as unpatentable under 35 U.S.C. §103(a) as being obvious over EP 1175915 in view of WO 01/70194.

Claims 3-8 stand rejected under 35 U.S.C. §103(a) as being obvious over '915 in view of WO 01/70194, which corresponds to English language document U.S. Patent No. 7,067,449 (hereinafter “Bess”). The Examiner cites to Bess for the proposition that certain solvents claimed by applicants may be incorporated in '915, and certain specific matrices may be employed, but the Examiner does not cite Bess for the proposition that a washing step could be added to '915. As noted above, '915 lacks any suggestion of Applicants claimed washing step. Bess also lacks any suggestion of a washing step, and the Examiner makes no argument that it adds support for such a step. Therefore this rejection should also be withdrawn.

In view of the above arguments, Applicants respectfully request reconsideration of the pending claims.

Claim Appendix

LISTING OF THE CLAIMS

1. **(original)** A process for producing a taste-masked composition comprising an ionic active compound and a functionalized polymer matrix, said process comprising the steps of loading said functionalized polymer matrix with said active compound to produce a loaded matrix, and washing said loaded matrix with a nonpolar solvent.
2. **(original)** The process of claim 1, wherein the ionic active compound is a basic active compound and the functionalized polymer matrix is a polymeric matrix having anionic functional groups.
3. **(previously submitted)** The process of claim 1, wherein the nonpolar solvent used for washing the loaded matrix is a solvent having a polarity index less than 5.
4. **(original)** The process of claim 3 wherein said solvent has a polarity index less than 3.
5. **(original)** The process of claim 3 wherein said solvent has a polarity index less than 1.
6. **(previously submitted)** The process according to claim 1, wherein said nonpolar solvent is selected from the group consisting of pentane, hexane, heptane, octane, cyclopentane, cyclohexane, methyl cyclohexane, ethyl cyclohexane, and carbon disulfide.
7. **(previously submitted)** The process according to claim 2, wherein the polymeric matrix having anionic functional groups used is a hydrogen form cation exchange resin, and wherein the active-loaded hydrogen form cation exchange resin obtained is further neutralized with a metal ion.
8. **(original)** The process of claim 7 wherein said metal ion is sodium or potassium.
- 9-15. **(cancelled)**

Evidence Appendix

None.

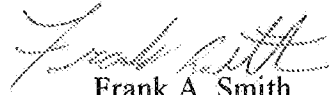
Related Proceedings Appendix

None.

In view of the above Applicants respectfully request favorable reconsideration of the application.

Dated: 3/2/10

Respectfully Submitted,



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